IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA, Plaintiff,	\$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$	CACE NO. 2.15 00251
V.	§	CASE NO. 3:15-cv-00371
SPECTRUM BRANDS, INC.,	\$ \$ &	
Defendant.	§ §	

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT SPECTRUM BRANDS, INC.'S OPPOSITION TO UNITED STATES OF AMERICA'S MOTION TO STRIKE OR OTHERWISE LIMIT EXPERT TESTIMONY OF ALAN SCHOEM AND JOHN MORRALL

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Defendant, Spectrum Brands, Inc. ("Spectrum"), submits this Memorandum of Law in Support of its Opposition to United States of America's Motion to Strike or Otherwise Limit Expert Testimony of Alan Schoem and John Morrall (Dkt. 102) (the "Motion") and states:

INTRODUCTION

The United States of America (the "Government") has moved to strike or otherwise limit the expert testimony of two of Spectrum's expert witnesses, Alan Schoem and John Morrall. (Dkt. 102). Both Mr. Schoem and Dr. Morrall formed their opinions on the basis of reliable information, and their opinions are relevant to the subject inquiry of this case and will be helpful to the trier of fact. The Government argues that the testimony by Mr. Schoem and Dr. Morrall would offer confusion rather than clarity, but that is only because the Government unilaterally rejects the defenses that Spectrum has interposed to its claims and therefore does not see the relevance of this testimony to those defenses. The testimony and opinions of Mr. Schoem and Dr. Morrall are admissible under Federal Rule of Evidence 702 and the principles of *Daubert* and should not be excluded.

The underlying basis for the Government's Motion is that the expert opinions and deposition testimony of Mr. Schoem and Dr. Morrall are not relevant to *the Government's* claims against Spectrum. However, the opinions of Mr. Schoem and Dr. Morrall support Spectrum's affirmative defenses in this case, including the argument that Spectrum did not have fair notice of the reporting obligations and that the CPSC acted in an arbitrary and capricious manner. The Government's apparent argument is that a company is required to submit a Section 15(b) report *anytime* it receives a consumer complaint regarding a product defect. If that were the only fact at issue in this case expert testimony would not be necessary. However, Spectrum is defending this case on the basis that the alleged defect in the Coffeemaker handle

did not present a substantial product hazard and, therefore, that it was not a reportable issue. Its defense is based on both constitutional and administrative law principles. Both Mr. Schoem and Dr. Morrall present expert opinions in support of the defenses based on these principles. The facts relied upon by both Mr. Schoem and Dr. Morrall are the type of facts and information relied upon by experts in the relevant field. Accordingly, the expert opinions and testimony of Mr. Schoem and Dr. Morrall are relevant and admissible under Federal Rule of Evidence 702.

FACTUAL BACKGROUND

Between January 2008 and April 2012, Spectrum, through its corporate predecessor Applica Consumer Products, Inc. ("Applica"), imported approximately 150,000 Black & Decker brand SpaceMaker Under-the-Cabinet Coffeemakers (the "Coffeemakers") and distributed them within the United States. (Dkt. 1, Compl. ¶ 17). The Complaint alleges that from February 2009 through October 2011 Applica received reports of incidents involving the handle of the glass carafe breaking while in use, allowing hot coffee to spill. (*Id.* ¶¶ 19-39). The vast majority of these reports did not involve personal injury but were complaints about the handle. (*Id.*). To the extent that there were any reports of injury, the injuries alleged involved burns or slight burns that often did not require medical treatment. (*Id.*). In fact, the Complaint alleges only one case of a claimant seeking medical attention (after she initially did not seek medical attention). (*Id.* ¶ 24).

Prior to its investigation in this case, CPSC staff analyzed other models of Spectrum coffeemakers on two separate occasions immediately prior to the time when the CPSC now alleges Spectrum should have reported the defect in *this* case. (Dkt. 78 at 10-25). In both cases, CPSC staff concluded that the coffeemakers contained defects that did not rise to the level of a "substantial product hazard" or "unreasonable risk of serious injury," notwithstanding allegations in one case of second-degree burns to several consumers, emergency department

treatments, and a scalding injury to the eye of a two-year old child with scarring and allegations in the other case of a burn injury to the face of an eight-year-old child, and second-degree burns to several consumers, some requiring medical treatment. *Id.* The CPSC's risk analysis of coffeemaker hazards in other products in the same timeframe confirmed that defects associated with minor (or even moderate) injury risks were, in nearly all cases, found not to present "a substantial product hazard" or "unreasonable risk of serious injury." *Id.*

The Complaint seeks civil penalties against Spectrum for alleged violations of the Consumer Product Safety Act ("CPSA"), 15 U.S.C. § 2051 (*Id.* ¶¶ 1-2). In Counts I and II of the Complaint, the Government alleges that Spectrum is liable for a civil penalty under the CPSA for failing to make a timely report under section 15(b) of the CPSA, 15 U.S.C. § 2064(b)(4). (*Id.* ¶¶ 51-54).

ARGUMENT

The issue in this case is whether Spectrum timely reported the Coffeemakers to the CPSC under the terms and conditions of the CPSA. In order to answer that question, the trier of fact must first determine whether Spectrum had a duty to report under Section 15(b) of the CPSA. Under Section 15 of the CPSA, a product must be reported to the CPSC if it contains a defect that could present a "substantial product hazard" or an "unreasonable risk of serious injury." 15 U.S.C. § 2064(b). In this case, Spectrum determined, based on the full scope of available information applicable to that determination, that the coffeemaker handle issue was not reportable under Section 15(b) of the CPSA.

Spectrum has disclosed Alan Schoem and John Morrall as expert witnesses, each of whom authored a report dated February 29, 2016. (Dkts. 71 and 72). Mr. Schoem was retained for "the purpose of providing expert opinion on the U.S. Consumer Product Safety

Commission's . . . processes and procedures, and on Spectrum Brands, Inc.['s] . . . current processes and procedures regarding reporting potentially hazardous products to CPSC." (Dkt. 72 (Schoem Report) at 1). Dr. Morrall was retained for "the purpose of providing expert opinion on the U.S. Consumer Product Safety Commission's . . . processes and procedures for assessing risks in connection with determining whether a particular product presents a Substantial Product Hazard." (Dkt. 71 (Morrall Report) at 1). The opinions of both Mr. Schoem and Dr. Morrall are relevant to the subject inquiry of whether the information available to Spectrum reasonably supported an obligation to report the Coffeemakers pursuant to Section 15(b) of the CPSA and whether the CPSC acted arbitrarily and capriciously in this matter. Furthermore, the opinions of both Mr. Schoem and Dr. Morrall are based on reliable facts and the product of scientifically valid methodology.

I. STANDARD FOR ADMISSIBILITY OF EXPERT TESTIMONY

Under Rule 702 and the principles enunciated by the Supreme Court in *Daubert*, the trial court must act as a "gatekeep[er]," ensuring that, prior to the admission of expert testimony, the testimony "both rests on a reliable foundation and is relevant to the task at hand." *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 597 (1993). Rule 702 provides:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. This Court has wide latitude in determining how to assess the reliability and relevance of the expert testimony at issue. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152-53 (1999).

A "reliable" expert opinion is one based on scientific, technical or other specialized knowledge, and not on belief or speculation. *Daubert*, 509 U.S. at 590. Although reliability is generally indicated by testing, peer review, evaluation of rates of error and general acceptability, the evaluation is a "flexible one." *Id.* Expert opinion testimony is reliable if it has "a reliable basis in the knowledge and experience of [the pertinent] discipline." *Id.* at 592.

An expert's testimony is "relevant" where it is "sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute." *Daubert*, 509 U.S. at 591 (internal citations omitted). An expert's testimony is relevant if it is likely to "assist the trier of fact to understand the evidence or to determine a fact in issue." *United States v. Hall*, 93 F.3d 1337, 1342 (7th Cir. 1996); *see also Smith v. Ford Motor Co.*, 215 F.3d 713, 721 (7th Cir. 2000)

("[I]n order for an expert's testimony to qualify as 'relevant' under Rule 702 it must assist the jury in determining any fact at issue in the case.")). The Seventh Circuit requires that courts evaluate "the state of knowledge presently existing about the subject of the proposed testimony in light of its appraisal of the facts of the case." *United States v. Brown*, 7 F.3d 648, 651-52 (7th Cir. 1993) (internal quotation marks omitted).

¹ The relevance consideration "has been aptly described . . . as one of 'fit." *Daubert*, 509 U.S. at 591. If the proffered testimony does not "fit" the purposes for which it is needed, it is irrelevant. *Id. (see also Chapman v. Maytag Corp.*, 297 F.3d 682, 687 (7th Cir. 2002) ("the suggested . . . testimony must 'fit' the issue to which the expert is testifying.") (quoting *Porter v. Whitehall Labs., Inc.*, 9 F.3d 607, 616 (7th Cir. 1993)).

II. ALAN SCHOEM'S EXPERT OPINIONS ARE RELEVANT, HELPFUL TO THE TRIER OF FACT AND BASED ON RELIABLE FACTS AND METHODOLOGY.

Alan H. Schoem, a former CPSC official, is a lawyer admitted to the bars of the state of Maryland and the District of Columbia who has been involved in product safety since 1973. (Dkt. 72 (Schoem Report) at 1-3; Dkt. 72-2 (Schoem CV) at 1-2). Mr. Schoem started at the CPSC in 1973, ultimately serving as the Associate Executive Director of the CPSC Office of Compliance from 1997 to 2004, a position in which he was responsible for the CPSC's enforcement programs. (*Id.*). Spectrum retained Mr. Schoem to opine on the CPCS's processes and procedures for evaluating whether a company has a reporting obligation and Spectrum's current policies and procedures for evaluating whether it has a reporting obligation based on the facts and information available to it at the relevant time. (Dkt. 72 (Schoem Report) at 1). In summary, Mr. Schoem concluded, first, that it was reasonable for Spectrum to conclude—based on the information available to it, including information provided by the CPSC itself—that it did not have to report the Coffeemaker handle issue to the CPSC. (*Id.* at 3). Second, he concluded that Spectrum currently has reasonable procedures in place to evaluate information to determine whether it has a reporting obligation to the CPSC. (*Id.*)

A. Mr. Schoem's Opinion That Spectrum's Decision Not To Report Was Reasonable Is Relevant To The Subject Inquiry.

The Government asserts that Mr. Schoem's expert opinions should be excluded from consideration because they are inadmissible legal conclusions and based on an incorrect legal standard. The CPSA requires a manufacturer to report under Section 15(b) where the information available to the manufacturer reasonably supports the conclusion that a product contains a defect that could create a "substantial product hazard" or an "unreasonable risk of serious injury or death." 15 U.S.C. § 2064(b). Spectrum's defense is based, in part, on the

theory that it did not have fair notice of what is reportable under the statute. (Dkt. 78 at 10-19). The lack of fair notice is based on the totality of information that was available to Spectrum at the time the Government alleges Spectrum was required to report. That information includes, among other things, correspondence from the CPSC indicating that products containing alleged defects that resulted in injuries more serious than those reported in this case were not substantial product hazards, which means they would not have been reportable under the CPSA.

Spectrum disclosed Mr. Schoem's expert opinion in support of its defense that, because of the lack of notice, Spectrum did not have a duty to report based on the scope of available evidence. The Government asserts that Mr. Schoem's opinions should be excluded because he opines on an ultimate issue of law. (Dkt. 103 at 5). Rule 704(a) of the Federal Rules of Evidence, however, states that "[a]n opinion is not objectionable just because it embraces an ultimate issue." Fed. R. Evid. 704; *Roundy's Inc. v. NLRB*, 674 F.3d 638, 648 (7th Cir. 2012). "There is a difference between stating a legal conclusion and providing concrete information against which to measure abstract legal concepts." *United States v. Blount*, 502 F.3d 674, 680 (7th Cir. 2007) (citing *United States v. Perkins*, 470 F.3d 150, 158-59 (4th Cir. 2006)).

Despite the Government's characterization of Mr. Schoem's analysis as one based solely on his personal opinion (Dkt. 103 at 7-8), as described by Mr. Schoem, the analysis is complex, as evidenced by differing conclusions reached by the CPSC. The analysis includes interpreting CPSC regulations (which permit the exercise of judgment), *see* pp. 9-10, *infra*, and information provided to a company by CPSC. Just as a physician in a medical malpractice case can testify to the reasonableness of a physician's conduct based on the standard of care, so Spectrum is entitled to have Mr. Schoem render an opinion based on his extensive experience, about what conclusion was appropriate for Spectrum to draw based on the information available to it.

Campbell v. United States, 904 F.2d 1188, 1193 (7th Cir. 1990) (affirming trial court's finding that defendant doctor did not deviate from applicable standard of care where defendant's expert witness testified that surgery was necessary and defendant doctor employed appropriate surgical techniques in performing the operation, even though Plaintiff's expert testified that he would have used several surgical techniques not utilized by defendant doctor).

Mr. Schoem is certainly aware of his role; as the Government notes in its Motion, Mr. Schoem testified that it is ultimately for the Court to decide whether Spectrum's assessment of the facts was reasonable and whether it was required to report based on the facts available to it in making that determination. (Dkt. 103 at 5). Mr. Schoem did not undertake to make that ultimate factual analysis himself, but rather opined that, based on the CPSC's communications with Spectrum, Spectrum would reasonably believe that it did not have a reporting obligation.

- **Q.** I'm not trying to be tricky about this. Again, I'm just trying to understand exactly what your opinion means. You're saying that Spectrum had the right to review all the information from both cases and compare them in determining whether it had a reporting obligation, right?
- **A.** Yes. Those -- it could look at those two cases plus all the information, the other information that it had in the current case and make its decision as to whether it believed it had a reporting obligation.
- **Q.** And when you opine at the end that Spectrum did not have an obligation to report, my question is, are you assuming that Spectrum undertook that analysis and that that analysis in fact showed that the cases were similar, or did you undertake that kind of factual analysis yourself?
- **A.** I did not undertake that factual analysis myself. I am saying that Spectrum could do that analysis and it would be reasonable for them to reach the conclusion that they didn't have a reporting obligation, but I didn't do that analysis.

(Dkt. 100 (Schoem Depo.) at 160:7 – 161:6).

The ultimate legal conclusion in this case is whether Spectrum was required to report the Coffeemaker handle issue to the CPSC. Mr. Schoem's expert opinion provides concrete information against which the court can measure those abstract legal concepts. *Blount*, 502 F.3d at 680. In *Sanders v. City of Chicago Heights*, No. 13-221, 2016 WL 1730608 (N.D. Ill. May 2, 2016), the Defendant sought to exclude Plaintiff's expert, Dr. Gaut on the basis that his opinion constituted an impermissible legal conclusion. *Id.* at *7-8. However, the court noted the distinction between offering opinions on impermissible legal conclusions and providing concrete information against which to measure abstract legal concepts, including relevant professional standards and a defendant's alleged deviations from those standards. *Id.* The Court ultimately held that Dr. Gaut was permitted to testify on the issue of whether the defendants' actions and policies were consistent with reasonable, typical practices and procedures in the relevant industry. *Id.* at *9 (*citing Hopkins v. City of Huntsville*, No. 13-429, 2014 WL 5488403, at *5 (N.D. Ala. Oct. 29, 2014).

The Government incorrectly contends in this case that there is no room for interpretation in deciding whether to report under Section 15 of the CPSA. That position, however, is directly contrary to the CPSC's own (interpretive) regulations, which among other things "illustrate by way of guidance the types of information the Commission believes a reasonable and prudent subject firm should consider *when deciding whether to report.*" Substantial Product Hazard Reports, CPSC, 43 Fed. Reg. 34,988, 34,993 (Aug. 7, 1978) (emphasis added). In fact, in the 1978 Interpretative Rule construing the meaning of the Section 15(b) reporting obligation, the Commission itself interpreted the obligation as triggered by the reasonable belief of the manufacturer as to whether a condition is reportable: "Congress intended that subject firms

report defects which they had sufficient reason to believe *could create* a substantial product hazard." 43 Fed. Reg. at 34,992 (emphasis in original).

This was confirmed in the 1992 revision of the Interpretative Rule: "In other cases, the firm may reasonably determine that the report or information does not reasonably support the conclusion that a reporting obligation exists." 57 Fed. Reg. 34,222, 34,225 (Aug. 4, 1992). Having been in charge of enforcing the CPSC's statutory authority and regulations for almost seven years, and having worked with them for over thirty years, Mr. Schoem is not only aware of the those statutory authorities and regulations, he is uniquely qualified to provide insights into them and how they apply to a company like Spectrum.

Contrary to the Government's assertions, Mr. Schoem does not misstate or rely on a different version of the statute or regulations. Rather, his opinion is based on the applicable language of the statute and regulations, as well as an interpretation of the other information that was available to Spectrum in making the determination whether to report. Neither Mr. Schoem nor Spectrum asserts that the CPSA or any interpretative regulations includes prior CPSC determinations on similar cases as part of its language. However, as Spectrum points out, it cannot be penalized for failing to report in this case, because it is entitled to rely on such information pursuant to constitutional principles, including fair notice. Mr. Schoem merely references those other sources of information to support his opinion that it was reasonable for Spectrum to rely on such information in making its determination whether to report.

B. Mr. Schoem's Expert Opinions Regarding Spectrum's Policies and Procedures Are Based on Reliable Facts and Methodology.

In this case, the Government baldly asserts both that Spectrum "has not implemented and maintained a reasonable and effective" compliance program (Dkt. 1, Compl. ¶ 49) and that there is a "reasonable likelihood" that Spectrum will continue to violate the provisions of the

CPSA (*id*. ¶ 50), and seeks injunctive relief on those facts alone.² So far, the only facts the Government has provided in response to discovery in support of *both* Spectrum's purported failure to have an adequate compliance program and the likelihood of Spectrum to fail to comply with the provisions of the CPSA in the future is Spectrum's alleged conduct in connection with this Coffeemaker. *See* June 27, 2016 Declaration of James Hemmings ¶ 2, Ex. 1, at 12-14. The Government has neither identified an expert on these topics or asserted in response to discovery that Spectrum's current policies are inadequate.

The Government asserts that Mr. Schoem's opinion regarding the adequacy of Spectrum's programs for ensuring compliance with the CPSA is based on insufficient facts or data. As noted above, Mr. Schoem was the head of the CPSC Office of Compliance for seven years. (Dkt. 72 (Schoem Report) at 2; Dkt. 72-2 (Schoem CV) at 1; Dkt. 72-3 (Schoem Dep.) at 107:18-20). Accordingly, he is intimately familiar with the CPSC's processes and procedures for evaluating alleged product defects and the information that is required to make a determination regarding whether a product has a "substantial product hazard." Following his career at the CPSC, Mr. Schoem worked as a consultant with Marsh USA for over seven years. (Dkt. 72 (Schoem Report) at 2; Dkt. 72-2 (Schoem CV) at 1; Dkt. 72-3 (Schoem Dep.) at 44:9-45:8). During his time working for Marsh, Mr. Schoem assisted companies in assessing CPSC compliance programs and ensuring that they were sufficient. (Dkt. 72-3 (Schoem Dep.) at 45:9-13).

The Government suggests that Mr. Schoem's evaluation of Spectrum's compliance policies was somehow deficient because he only reviewed approximately 50 pages of company

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² Spectrum has moved to dismiss the Government's claim for injunctive relief, and the motion remains pending. Defendant Spectrum Brands, Inc.'s Motion to Dismiss Count IV of Plaintiff's Complaint for Failure to State a Claim (Dkt. 6), Memorandum of Law in Support of Defendant Spectrum Brands, Inc.'s Motion to Dismiss Count IV of Plaintiff's Complaint for Failure to State a Claim (Dkt. 8).

documents and relied on information provided by Spectrum's Senior Director of Quality and Regulatory Compliance. (Dkt. 103 at 8). In support of that suggestion, the Government claims that Mr. Schoem's review in this case was vastly inferior to the type of evaluation he performed while working as a consultant for Marsh USA. The Government claims that the kind of review Mr. Schoem performed as a consultant displayed the "intellectual rigor" required of expert testimony. (Dkt. 103 at 9). However, as evidenced by Mr. Schoem's deposition testimony and the review he conducted in this case, he performed the same type of analysis that he would have performed while working as a consultant:

- **Q.** So typically when you would go -- again, we're talking about your time at Marsh -- when you would go and assess a company's compliance programs for CPSC, what kind of review would that entail?
- **A.** It could entail going into the facility and talking to key employees, key executives who had responsibility in different product areas. In other cases it might be doing phone interviews with individuals within the company and then looking at their existing documents to see what they said.
- **Q.** And what kind of existing documents would you review?
- **A.** Any documents that they had in place that dealt with how they evaluated safety of products. So we would look at things like consumer complaints or how they maintained or collected information about consumer complaints, incident reports, call center information, quality control information, how they collected this information, whether they maintained it in a central database, for example, whether they had a committee that evaluated this information routinely, periodically, whether they had persons who were responsible for making decisions on whether there was a reporting obligation, whether they had an escalation procedure within the company to get a complaint that might go into a call center to somebody at a higher level who would be deciding whether to report to a regulatory agency.

(Dkt. 72-3 (Schoem Dep.) at 48:1 - 49:6).

The documents that Mr. Schoem described as part of his review as a consultant are precisely the types of documents he reviewed in this case. (Dkt. 72-1 (Schoem Documents Reviewed) at 1-2). The Government misstates that Mr. Schoem testified that he "entirely relied on what Mr. Stamp told [him]." (Dkt. 103 at 9.) The excerpt of Mr. Schoem's deposition cited by the Government refers to the portion of Mr. Schoem's report where he discusses the role of Spectrum's legal department. Mr. Schoem was merely clarifying that he gathered the information applicable to this portion of the report through his conversations with Mr. Stamp. Mr. Schoem makes clear throughout his report and deposition that his opinions are based both on his conversations with Mr. Stamp and the Spectrum documents that he reviewed. (Dkt. 72 (Schoem Report) at 1, 17; Dkt. 72-3 (Schoem Dep.) at 53:21-54:12).

The Government does not describe the type of additional information or documentation that Mr. Schoem should have reviewed in forming his opinion in this case. Nor does the Government identify any other individuals within the organization that would be necessary for Mr. Schoem to form a complete opinion. Mr. Schoem based his opinions on a review of Spectrum's applicable documents for its CPSC compliance processes and procedures, along with information obtained from Spectrum's Senior Director of Quality and Regulatory Compliance. Accordingly, Mr. Schoem relied on sufficient facts and data in forming his opinions.

Finally, the Government claims that Mr. Schoem's expert opinions should be excluded because (a) he does not utilize a reliable methodology in reaching his opinions and (b) those opinions are not helpful because he only knows how the company's compliance programs appear on paper and he has no idea how they function in reality. (Dkt. 103 at 10). Mr. Schoem has been proffered as an expert on Spectrum's current processes and procedures regarding

reporting potentially hazardous products to CPSC (Dkt. 72 (Schoem Report) at 1), and he testified that this was the type of work he did as a consultant with Marsh USA (Dkt. 72-3 (Schoem Dep.) at 44:9 – 45:13). The Government does not articulate what it considers to be the appropriate expert methodology for Mr. Schoem to have utilized, nor does it articulate how Mr. Schoem apparently deviated from any such methodology. It is difficult to conceptualize what exactly the Government expects Mr. Schoem to have done, beyond the analysis that he undertook, in order to evaluate how Spectrum's compliance policies function in reality.

Mr. Schoem is not a Spectrum employee and does not have the benefit of working for the organization as it utilizes the processes and procedures described in his report. In order to reach an expert opinion in this matter, Mr. Schoem reviewed Spectrum's internal documents and interviewed its Senior Director of Quality and Regulatory Compliance. Based on that review, his evaluation of Spectrum's compliance program, and his extensive experience in the relevant field, Mr. Schoem was able to opine that the policies and procedures were reasonable. In so doing, Mr. Schoem formed his opinions on the basis of the same reliable methods that other experts in the field would use. One wonders how someone would evaluate a compliance program if not by reviewing its documentation and interviewing an employee at the hub of the company's product safety compliance activity with respect to home appliances. If these claims go to trial, will the Government object to Spectrum introducing its present policies into evidence and presenting testimony about them in defense?

As described above, Mr. Schoem's expert opinions are relevant, helpful to the trier of fact, based on sufficient facts and data, and the product of reliable expert methodology.

Accordingly, Mr. Schoem should be permitted to testify and provide expert opinions regarding

the CPSC's policies and procedures, along with the reasonableness of Spectrum's policies and procedures for evaluating whether to report a potential substantial product hazard.

III. DR. JOHN MORRALL'S EXPERT OPINIONS ARE RELEVANT, HELPFUL TO THE TRIER OF FACT AND BASED ON RELIABLE FACTS AND METHODOLOGY.

A. Dr. Morrall Is Qualified To Render Expert Opinions On Risk Assessment.

It is unclear whether the Government challenges Dr. Morrall's qualifications to render expert opinions in this matter. The Government appears to criticize Dr. Morrall's lack of experience with CPSC risk assessments specifically, but recognizes the significant experience he has with risk assessments generally over the course of his 40-year career. (Dkt. 103 at 11-12). A witness does not need to possess the requisite experience within the specific field of testimony, but must be qualified through experience to render the opinions generally. Pages-Ramirez v. Ramirez-Gonzalez, 605 F.3d 109, 114 (1st Cir. 2010) (expert testimony should not be excluded if it would otherwise help the factfinder understand a fact in issue on the basis that the expert does not have the specialization thought of as "most appropriate."); Compton v. Subaru of Am., Inc., 82 F.3d 1513, 1520 (10th Cir. 1996) (explaining that so long as the expert keeps "within the reasonable confines of his subject area, . . . a lack of specialization does not affect the admissibility of [the expert] opinion, but only its weight" (internal quotation marks omitted)); see also Ford Motor Co., 215 F.3d at 721 ("While 'extensive academic and practical expertise' in an area is certainly sufficient to qualify a potential witness as an expert . . . 'Rule 702 specifically contemplates the admission of testimony by experts whose knowledge is based on experience.' Thus, a court should consider a proposed expert's full range of practical experience as well as academic or technical training when determining whether that expert is qualified to render an opinion in a given area." (internal citations omitted)).

Dr. Morrall served for over twenty years in senior executive positions at the Office of Information and Regulatory Affairs of the U.S. Office of Management and Budget with responsibility for directing compliance with Presidential Executive Orders on regulatory policy and risk assessment. (Dkt. 71 (Morrall Report) at 1; Dkt. 71-1 (Morrall CV) at 1-3). He worked for a total of 33 years for two White House offices: the Office of Management and Budget (OMB) from 1981 to 2008 and the Council of Wage and Price Stability from 1975 to 1981. (*Id.*) Throughout his career he has reviewed hundreds of risk assessments from over a dozen agencies, including the CPSC, DOT, OSHA, FDA, and EPA. (*Id.*) Dr. Morrall has also participated in formulating guidance on best practices for regulatory analyses and risk assessments for the US, Organization for Economic Cooperation and Development (OECD), EU, Asia-Pacific Economic Cooperation (APEC) and several individual countries. (*Id.*) Dr. Morrall has published several academic articles on these subjects. (*Id.*) There is no question that Dr. Morrall, an economist who has been evaluating risk assessments for the past 40 years, is qualified to render the expert opinions as outlined in his report.

B. Dr. Morrall's Opinions Are Relevant To The Subject Inquiry.

Unquestionably, Dr. Morrall's opinions are relevant to the subject inquiry of this case. Spectrum has asserted numerous defenses to the Government's claims, including a lack of fair notice and agency action that is arbitrary and capricious. (Dkt. 78 at 10-25). As described more fully in Spectrum's Motion for Summary Judgment, in light of the Commission's conclusions that defects in Spectrum's coffeemakers in the relevant time period did not present a substantial product hazard or unreasonable risk of serious injury, Spectrum did not have fair notice that the Commission would decide in 2014 that Spectrum was required to report a potential substantial product hazard of the kind alleged by the Commission in this case. (Dkt. 78 at 10). Moreover,

the Commission's repeated conclusions that coffeemakers with defects more hazardous than those of the Coffeemaker were not substantial product hazards makes its action penalizing Spectrum arbitrary and capricious. (Dkt. 78 at 19-25).

While the Government would prefer that the sole focus of this case be Spectrum's conduct evaluated in a vacuum, due process requires that this Court evaluate more. "A fundamental principle in our legal system is that laws which regulate persons or entities must give fair notice of conduct that is forbidden or required." *FCC v. Fox TV Stations, Inc.*, 132 S. Ct. 2307, 2317 (2012); *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972). In addition to providing a lack of fair notice, the Commission's conclusion that Spectrum violated Section 15(b) of the CPSA is arbitrary and capricious. (Dkt. 78 at 19-25).

An expert's opinion is relevant if it will assist the trier of fact to determine any fact at issue. *Ford Motor Co.*, 215 F.3d at 721. In this case, Dr. Morrall explained in his report that "basic, well-accepted risk assessment principles" involve using the "best available scientific information, consistency in determinations, transparency of decisions about risk assessments in particular cases, completeness in the characterization of risks and application of risk evaluation factors, identification of uncertainties in the risk analysis, priority setting, risk comparisons, Cost-Effectiveness analysis, countervailing risks, and special attention to vulnerable groups such as children." (Dkt. 71 (Morrall Report) at 8). The evidence demonstrates that the CPSC's policies and procedures do not conform to those risk assessment principles. (Dkt. 78 at 19-25). Dr. Morrall's opinions are relevant to that evaluation and should not be excluded.

C. Dr. Morrall's Expert Opinions Are Based On Reliable Facts And Methodology.

The Government claims that Dr. Morrall's testimony is based on insufficient facts, data, and expertise because he relied on "a single CPSC employee manual" and certain files relating

to other CPSC coffeemaker investigations. (Dkt. 103 at 14-15). It is ironic that the Government now claims Dr. Morrall's reliance on this employee manual is insufficient, when its own witnesses testified that they relied on that same manual in performing their duties. *See* Dkt. 77 at 19, ¶ 113 (Tanya Topka confirmed at her deposition that at the time of the investigation that led to this lawsuit, the staff relied on "the compliance manual."); *id.* at 18, ¶ 112 (Judith Hayes, the compliance officer who determined in 2008 that hot water exposure from Home Café coffeemakers was not a substantial product hazard or an unreasonable risk of serious injury, could not even remember the name of the manual that she and other compliance officers "were given [] to follow."). In fact, Spectrum requested through discovery the "section 15 manual" as described by Ms. Dahlman at her deposition. (Dkt. 76-18 at 10). In response, the Government produced an April 2002 CPSC employee manual. (Dkt. 76-2).

The Government also claims that Dr. Morrall's opinions are inadmissible because he did not speak with anyone at the CPSC, is unaware of how the CPSC operates generally and did not know whether CPSC employees received training other than what was in the manual. However, Bini Dahlman, the compliance officer for the Carafe Handle Issue that is the subject of this case, testified that she did not recall receiving any training on making preliminary determinations of hazard other than what is contained in the manual. (Dkt. 77 at 20, ¶ 119.) The Government does not claim what additional materials or information Dr. Morrall should have relied upon in forming his opinions. And in fact, based on the testimony of the Government's own witnesses, it appears as though the information and materials that Dr. Morrall reviewed are the same materials relied upon by the CPSC in making preliminary determinations of hazard.

As for the files relating to other CPSC coffeemaker investigations, as noted by the Government, some of those files which were reviewed by Dr. Morrall were slim, and he had

little to go on in trying to determine how the CPSC actually evaluated particular products.

Indeed, the materials reviewed by Dr. Morrall were the only materials produced by the Government in response to Spectrum's discovery requests. The Government argues that Dr. Morrall's opinions are inadmissible because they are based on his review solely of those materials produced in discovery. Dr. Morrall can hardly be criticized for not reviewing enough materials when those materials are simply unavailable. Accordingly, Dr. Morrall relied on sufficient facts and data and used a reliable methodology in forming his opinions, and his testimony should not be excluded.

CONCLUSION

For the foregoing reasons, Spectrum Brands Inc. respectfully requests that the Court deny the United States of America's Motion to Strike or Otherwise Limit Expert Testimony of Alan Schoem and John Morrall.

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